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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,290	09/29/2003	Gregory A. Demopulos	PH.1.0006.US2	3124

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,290	DEMOPULOS ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40, 42-51, 53-61* is/are pending in the application.

4a) Of the above claim(s) *48-50 and 59-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,42-47,51 and 53-58* is/are rejected.

7)☐ Claim(s) _ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of applicant's filing of an amendment on 03/14/2007. By the amendment, claims 40 and 51 have been amended and claims 41, 52 and 62-64 have been cancelled.

2. Claims 40, 42-47, 51 and 53-58 are currently pending for prosecution on the merits.

3. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40-47, 51-58 and 62-64are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific restenosis inhibitory agent such as "hirudin, hirulog, clopidogrel, ticlopidine, ridogrel, CY 1748, c7E3, MK-383, RO 4483, integrin, calphostin C, G-6203, GF 109203X, bisindoylmaleiminde I, lavendustin A, tyrphostin AG1296, tyrphostin AG1295 and staurosporine" and "the specific spasm inhibitory agents such as "nisoldipine, nifedipine, nimodipine, lacidipine, isradipine, amlodipine, BQ 123, FR 139317, BQ 610, nitroglycerin, sodium nitroprusside, SIN-1, SNAP, FK 409, FR 144420, cromakalim, nicorandil, minoxidil, P 1075, KRN 2391, pinacidil, amitriptyline, imipramine, trazodone, desiprmaine, ketanserin, does not reasonably provide enablement for "inhibition of restenosis",

"inhibiting spasm", "direct thrombin inhibitor and receptor antagonist, purinoceptor receptor antagonists, thromboxane inhibitors and receptor antagonists...", "spasm inhibitor agents" or "serotonin2 receptor subtype antagonists, nitric oxide donors, ATP-sensitive potassium channel openers...". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

With respect to scope of enablement of "spasm inhibitory agent", "restenosis inhibitory agent selected from the group consisting of: (a) antiplatelet agents...", "spasm inhibitor agents" or "spasm inhibitor agent is selected from the group consisting of: serotonin2 receptor subtype antagonists...". ,

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and

biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright, 458 F. supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5(BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of compositions of adrenocorticotropic hormones was unpredictable art; In re Wright, 9999 F.2d 1577, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of inhibiting restenosis or spasm prior to filling of the instant invention was an unpredictable art.

The claims are very broad due to the vast number of possible compounds of that are described as being "spasm inhibitory agent", "direct thrombin inhibitors and receptor antagonists, purinoceptor receptor antagonists, thromboxane inhibitors and receptor antagonists, platelet membrane glycoprotine receptor antagonists, inhibitors of cell adhesion molecules, selectin inhibitors, integrin inhibitors, anti-chemotactic agents, interleukin receptor antagonists, protein kinase C inhibitors and protein tyrosine kinase inhibitors, modulators of intraceullar protein tyrosine phosphatase, inhibitiors of src homology2 domains" or "serotonin2 receptor

subtype antagonists, tachykinin receptor antagonist, nitric oxide donors, ATP-sensitive potassium channel openers, calcium channel antagonists and endothelin receptor antagonists". The instant claims cover plethora of compounds having the claimed desired characteristic that are known to exist and those that may be discovered in the future, for which there is no enablement provided.

Although the specification discloses "hirudin, hirulog, clopidogrel, ticlopidine, ridogrel, CY 1748, c7E3, MK-383, RO 4483, integrin, calphostin C, G-6203, GF 109203X, bisindoylmaleiminde I, lavendustin A, tyrphostin AG1296, tyrphostin AG1295 and staurosporine" as the suitable examples of direct thrombin inhibitors and receptor antagonists, purinoceptor receptor antagonists, thromboxane inhibitors and receptor antagonists, platelet membrane glycoprotine receptor antagonists, inhibitors of cell adhesion molecules, selectin inhibitors, integrin inhibitors, anti-chemotactic agents, interleukin receptor antagonists, protein kinase C inhibitors and protein tyrosine kinase inhibitors, modulators of intraceullar protein tyrosine phosphatase, inhibitiors of src homology2 domains" and "nisoldipine, nifedipine, nimodipine, lacidipine, isradipine, amlodipine, BQ 123, FR 139317, BQ 610, nitroglycerin, sodium nitroprusside, SIN-1, SNAP, FK 409, FR 144420, cromakalim, nicorandil, minoxidil, P 1075, KRN 2391, pinacidil, amitriptyline, imipramine, trazodone, desiprmaine, ketanserin" as the suitable examples of "serotonin2 receptor subtype antagonist, tachykinin receptor antagonist, nitric oxide donors, ATP-sensitive potassium channel openers, calcium channel antagonists and endothelin receptor antagonists", the specification fails to provide how to make/screen "spasm inhibitory agent", "direct thrombin inhibitors and receptor antagonists, purinoceptor receptor antagonists, thromboxane inhibitors and receptor antagonists, platelet membrane glycoprotine

receptor antagonists, inhibitors of cell adhesion molecules, selectin inhibitors, integrin inhibitors, anti-chemotactic agents, interleukin receptor antagonists, protein kinase C inhibitors and protein tyrosine kinase inhibitors, modulators of intraceullar protein tyrosine phosphatase, inhibitiors of src homology2 domains" or "serotonin2 receptor subtype antagonists, tachykinin receptor antagonist, nitric oxide donors, ATP-sensitive potassium channel openers, calcium channel antagonists and endothelin receptor antagonists" without undue amount of experimentation and make further modification to arrive the claimed combination. The instant claims read on any compounds having the claimed characteristics, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

As discussed above, biological compounds often react unpredictably under different circumstances. For example, contrary to the instant invention, dilitiazem (calcium channel antagonist) and heparin (thrombin inhibitor) are known to be ineffective in the treatment of restenosis ("Inefficacy of dilitiazem in restenosis prevention after coronary angioplasty", Tanajura et al., Arq Bras Cardiol., abstract, 1994, 62(2):99-102; "Does Heparin Cofactor II modulate Athersclerosis and Restenosis", D. Tollefsen, Circulation 2004, 109;2682-2684). Thus, to practice the instant invention to the claimed scope, applicant would have to make or screen numerous possible compounds that are known to have the desired characteristic of the instant invention (may be over >1000 or >10,000) and then undergo undue trials and errors to find the desired combination. In other words, the instant invention necessitates for the skilled artisan to undergo an exhaustive search for the embodiments suitable to practice the claimed invention.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fishcher, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575.

As discussed above, considering above factors, especially the "sufficient working examples", "the level of skill in the art", "the relative skill and the unpredictability in the pharmaceutical art", "breadth of the claims" and "the chemical nature of the invention", one having ordinary skill in the art would have to undergo an undue amount of experimentation to make the claimed compositions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 40-42, 44-47, 51-58 and 62-64 rejected under 35 U.S.C. 103(a) as being unpatentable over Krongrad (US 5786362) in view of Honn et al. (US 4906646).

Krongrad teaches the use of protein kinase C inhibitor such as calphostin C for the treatment of hormone independent cancer including breast, prostate, uterine, ovarian and colon cancer (abstract; column 8, line 31 and lines 39-45).

Honn et al. (US 4906646) teaches the use of calcium channel blocker such as nifedipine for the treatment of cancer including colon, ovarian, testicular and bladder cancer (column 8, lines 24-26; column 13, lines 5-6), wherein said calcium channel blocker is administered between about 0.01 and 20 mg per kg of body weight of the mammal (claims 1-3); and wherein

the calcium channel blocker is formulated into aqueous solution where said formulation is prepared by mixing water, physiological saline or Ringer's solution (column 8. lines 14-21).

The teaching of Krongrad differs from (i) the claimed invention in the single composition and (ii) the specific dosage concentration, namely "no greater than 100,000 nanomolar" or "no greater than 10,0000 nanomolar"(claims 41-42, 52-53) or "1.0 to 10,000 namomolar for calcium channel antagonist" (claims 47 and 58); and the incorporation of irrigation fluid (claims 43 and 54); and the liquid dosage formulation containing biocompatible solvent, a suspension, a polymeriazble or non-polymerizable gel, paste and a salve (claims 44 and 55).

Above references in combination make clear that protein kinase C inhibitor and nifedipine have been individually used for the treatment of colon cancer or ovarian cancer. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

With respect to the dosage concentration of each active ingredients, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ233, 235 (CCPA 1955). See also In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

With respect to the incorporation of irrigation fluid (the specification discloses "normal saline or lactated Ringer's as the suitable example of irrigation fluid, see page 2, lines 9-10) or

liquid carrier such as "a biocompatible solvent, a suspension, a polymerizable or non-polymerizable gel, a paste and a salve", those of ordinary skill in the art would have been readily determined the appropriate dosage forms containing the claimed secondary ingredients (e.g., physiological saline or lactated Ringer's solution) or liquid carrier (e.g., biocompatible solvent or suspension) for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage forms or delivery systems disclosed the cited reference(s).

Response to Arguments

6. Applicant's arguments filed March 14, 2007 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that the instant specification is "full of support from the literature for the anti-restenotic, anti-spasm or anti-inflammatory effects of the individual claimed agents". Applicant alleges that "routine assays are known to those of skill in the art that can be used should there be a question as to whether a given agent is within the scope of the invention, which assay are cited in the literature referenced throughout the specification".

This argument is not considered persuasive. As discussed in preceding comments, biological compounds often react unpredictably under different circumstances. For example, contrary to the instant invention, dilitiazem (calcium channel antagonist) and heparin (thrombin inhibitor) are known to be ineffective in the treatment of restenosis ("Inefficacy of dilitiazem in restenosis prevention after coronary angioplasty", Tanajura et al., Arq Bras Cardiol., abstract,

1994, 62(2):99-102; "Does Heparin Cofactor II modulate Athersclerosis and Restenosis", D. Tollefsen, Circulation 2004, 109;2682-2684). Thus, to practice the instant invention to the claimed scope, applicant would have to make or screen numerous possible compounds that are known to have the desired characteristic of the instant invention (may be over >1000 or >10,000) and then undergo undue trials and errors to find the desired combination. In other words, the instant invention necessitates for the skilled artisan to undergo an exhaustive search for the embodiments suitable to practice the claimed invention.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fishcher, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575.

As discussed above, given the breadth, the disparate nature of compounds that is presently claimed, the highly unpredictable state of the art where many specific differences or different physicochemical properties are existed among unrelated structural compounds or even structurally related compounds, and the insufficient amount of guidance present in the specification, one of ordinary skill in the art would be burdened with undue "painstaking

experimentation study" to make/use the claimed "sodium-channel inhibiting substance" that would be enabled in this specification (The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether is required to make and use the instant invention. "the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 858 F.2d 737, 8 USPQ2d 1404 (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976))).

The examiner acknowledges that the Office does not require the present of (all) working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use the full scope of the presently claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the data shown is a reasonably representative and objective showing such that it was commensurate in scope with and, thus, adequately enables, the use of the elected species for the full scope of the presently claimed subject matter. Absent such evidence or reasoning, applicant has failed to obviate the rejection of the instant claims under 35 USC 112, first paragraph (for the lack of scope of enablement).

Applicant's argument in the response takes the position that "there is complete absence of disclosure of local delivery, or the use of a carrier suitable for local delivery, or suitable for

perioperative vascular delivery". Applicant alleges that neither Krongrad nor Honn is concerned with the instantly inhibiting restenosis or locally delivered composition.

This argument is not found persuasive. Unlike the applicant's argument, recitations of functional property or characteristic of each of ingredient or statements of intended use or purpose are not limited to the interpretation of the composition claims. Thus, the references in combination make obvious the instant invention.

It is noted that ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer."); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001)

Conclusion

7. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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